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| EXAMINER | |
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| MORGAN, ROBERT W | |
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| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/556,945 | MARKS, JAMES D. | |
| | Examiner | Art Unit | |
| | Robert W. Morgan | 3626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *204-253* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *204-253* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Notice to Applicant*

1. This communication is in response to the amendment filed 11/10/06 the following has occurred: Claims 225 has been amended. Claims 204-253 are presented for examination.

### *Claim Objections*

2. The claim objection to claim 225 has been withdrawn by the Examiner based on the changes made by the Applicant to the claims.

### *Specification*

3. The Examiner has withdrawn the objection to under 35 U.S.C. 132 because it introduces new matter into the disclosure based on the pointed to passages from the Applicant's specification.

### *Claim Rejections - 35 USC § 112*

4. The rejections under 35 U.S.C. § 112, first paragraph have been withdrawn by the Examiner.

### *Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 204-209, 215-221, 224-229, 231-236 and 239 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by U.S. Patent Application Publication 2002/0002474 to Michelson et al.

As per claim 204, Michelson teaches a method of acquiring information from individuals volunteering for ongoing consideration as potential candidates for participating as research subjects in any of a plurality of clinical trials identified as currently recruiting research subjects, by means of a server operated by a recruitment service provider, the server being configured to communicate with a plurality of end-user computer terminals via a network, the method comprising the steps of:

--the claimed server transmitting for display on one end-user terminal a health survey form accessible to one of the individuals, the health survey form soliciting from the individual contact information by which the individual may be contacted, and at least one of the individual's personal and medical information, whereby the individual agrees to volunteer to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in any of the plurality of clinical trials is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A)(see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip

code, medical conditions experienced by the user and telephone number (see: paragraph 97). Furthermore, Michelson et al. teaches in area 650, the user is asked to agree to terms and conditions governing the system and upon completion of the required information and accepting the terms and conditions, the user become a registered users (see: paragraph 97);

--the claimed server receiving information transmitted by the individual via the one end-user computer terminal, the information containing the individual's contact information and the at least one of the individual's personal and medical information is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using computer a such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97); and

--the claimed server storing the at least one of the individual's contact information and the at least one of the individual's personal and medical information in a database, thereby registering the individual for ongoing consideration as a potential candidate for participating as a research subject in any of the plurality of clinical trials that is identified by the recruitment service provider as currently recruiting candidates, wherein the individual's ongoing consideration comprises consideration for any of the plurality of clinical trials registered with the

recruitment service provider at or after the time when the individual is first registered by the server is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches that a subject uses the secure web page to answer all questions in the questionnaire and the answers are stored in the subject database with consent from the patient (see: paragraph 113 and Figs. 15A-15F).

As per claim 205, Michelson et al. teaches the claimed information received by the server signifies an agreement by the individual to release the contact information to the representative of the at least one matching clinical trial. This limitation is met at step 2040, where after the subject has registered, the inventive system ask the subject for permission to receive notices about clinical studies (see: paragraph 165). In addition, Michelson et al. teaches that clinical study sponsors, investigators and subjects may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81).

As per claim 206, Michelson et al. teaches the claimed health survey form solicits the identification of one or more medical conditions of the individual for which the individual wishes to be considered as a potential candidate for participating as a research subject in one or more of the plurality of clinical trials. This limitation is met by the registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be

required to provide information such as an indication of one or more medical conditions in which the user is interested (see: paragraph 97).

As per claim 207, Michelson et al. teaches the claimed health survey form solicits the identification of one or more clinical researchers for whom the individual wishes to be considered as a potential candidate for participating as a research subject in any of the plurality of clinical trials that are associated with the one or more clinical researchers. This feature is met at area 607, where a registered user may select up to three therapeutic area (clinical research areas) in which the user is interested (see: paragraph 95).

As per claim 208, Michelson et al. teaches the claimed network comprises one or more of the Internet, the World Wide Web, an intranet, a local area network, a wide area network and a wireless communications network. The limitation is met by the network (103, Fig. 1A) being the Internet (see: paragraph 80).

As per claim 209, Michelson et al. teaches the claimed step of:

--the claimed server transmitting registration information for display on a second end-user computer terminal, said registration information soliciting information for registering a clinical researcher administering one or more of the plurality of clinical trials. This feature is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches that an investigator who is interesting in conducting a clinical study may register on the professional site (see: paragraph 99 and Figs. 1B, 7A-7C).

As per claim 215, Michelson et al. teaches a method of on-line recruitment of volunteers for ongoing consideration as potential candidates for participating as research subjects in any of a plurality of clinical trials, by means of a server operated by a recruitment service provider, the server being configured to communicate with a plurality of end-user computer terminals via a network, the method comprising the steps of:

--the claimed server receiving first information transmitted by one of the individuals via one of the plurality of end-user computer terminals, the first information containing contact information for contacting the individual, and at least one of personal and medical information for the individual, whereby the individual agrees to volunteer to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in any of the plurality of clinical trials identified to the recruitment service provider by a representative of the trial as currently recruiting candidates is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A)(see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97). Furthermore, Michelson et al. teaches in area 650, the user is asked to agree to terms and

conditions governing the system and upon completion of the required information and accepting the terms and conditions, the user become a registered users (see: paragraph 97);

--the claimed comparing the at least one of personal and medical information to selection criteria of at least one of the plurality of clinical trials that are identified to the recruitment service provider as currently recruiting candidates is met by the system evaluating information with respect to the person's possible selection for a clinical study such as querying the database based on a disease condition of interest indicated by the subject; other information from the registration of the subject or prior questionnaire completed by the subject (see: paragraph 166);

--the claimed selecting the individual as a potential candidate for participating as a research subject in at least one of the identified clinical trials for which the comparison of the at least one of personal and medical information to the selection criteria indicates a match is met at met at step 2050, where if data regarding a person matches data related to clinical study, the system provides notification to the person or caregiver (see: paragraph 167). The Examiner considers the data regarding a person to include personal and medical information; and

--the claimed providing the individual's contact information to a representative of the at least one matching clinical trial, whereby the representative may contact the individual directly to further evaluate the individual as a candidate for participating as a research subject in the matching clinical trial is met after the pre-screening process, a list of pre-screened subjects who may be eligible to participate in a clinical study is given to the investigator and at step 826, the investigator schedule an appointment with each of the subjects on his or her pre-screened list (see: paragraph 114).

As per claim 216, Michelson et al. teaches the claimed information received by the server signifies an agreement by the individual to release the contact information to the representative of the at least one matching clinical trial. This limitation is met at step 2040, where after the subject has registered, the inventive system ask the subject for permission to receive notices about clinical studies (see: paragraph 165). In addition, Michelson et al. teaches that clinical study sponsors, investigators and subjects may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81).

As per claim 217, Michelson et al. teaches the steps of:

--the claimed server transmitting a participation agreement for display on one of the plurality of end-user terminals accessible to an individual, the participation agreement soliciting consent from the individual to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in at least one of the plurality of clinical trials that are identified by the recruitment service provider as currently recruiting candidates is met by clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches at step 2040, that after a user has register by completing the registration form, the system asks the person or caregiver to provide simple consent to add the person's information to the database and to give permission to receive notices about clinical studies (see: paragraph 165); and

--the claimed server receiving a signal transmitted by the one of the plurality of end-user terminals indicating the individual's consent to the participation agreement is met when in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97). Furthermore, Michelson et al. teaches in area 650, the user is asked to agree to terms and conditions governing the system and upon completion of the required information and accepting the terms and conditions, the user become a registered users (see: paragraph 97).

As per claim 218, Michelson et al. teaches the claimed information transmitted by the individual includes personally-identifying information of the individual. This limitation is met when a user want to register as a user with the subject database, he or she will be required to provide information such as first and last name, electronic mail address, zip code, medical conditions experienced by the user and telephone number and additional information such as date of birth (see: paragraph 97).

As per claim 219, Michelson et al. teaches the claimed personally-identifying information includes a name of the individual and a second personal identifier of the individual. This limitation is met when a user want to register as a user with the subject database, he or she will be required to provide information such as first and last name, electronic mail address, zip code, medical conditions experienced by the user and telephone number and additional information such as date of birth (see: paragraph 97).

As per claim 220, Michelson et al. teaches the claimed second personal identifier is a date of birth of the individual. This limitation is met when a user want to register as a user with the

subject database, he or she will be required to provide information such as first and last name, electronic mail address, zip code, medical conditions experienced by the user and telephone number and additional information such as date of birth (see: paragraph 97).

As per claim 221, Michelson et al. teaches the claimed personally-identifying information includes a unique registration number of the individual. This limitation is met when a user want to register as a user with the subject database, he or she will be required to provide information such as first and last name, electronic mail address, zip code, medical conditions experienced by the user and telephone number and additional information such as date of birth (see: paragraph 97).

As per claim 224, Michelson et al. teaches the claimed network comprises one or more of the Internet, the World Wide Web, an intranet, a local area network, a wide area network and a wireless communications network. The limitation is met by the network (103, Fig. 1A) being the Internet (see: paragraph 80).

As per claim 225, Michelson et al. teaches the step of:

--the claimed receiving a match query from the representative of the at least one clinical trial, wherein the match query identifies the selection criteria for determining the match is met at step 2146, where the inventive system identifies an investigator based upon the query results and the investigator's practice setting such as the disease condition associated with the specific clinical study used (see: paragraph 147).

As per claim 226, Michelson et al. teaches a method of on-line recruitment of volunteers for ongoing consideration as potential candidates for participating as research subjects in any of a plurality of clinical trials, by means of a server operated by a recruitment service provider, the

server being configured to communicate with a plurality of end-user computer terminals via a network, the method comprising the steps of:

--the claimed server receiving health survey information transmitted by one of the individuals via one of the plurality of end-user computer terminals, the health survey information including contact information for contacting the individual, opt-in information indicating one or more selected clinical trial researchers, and at least one of personal and medical information for the individual, wherein by transmitting the health survey information, the individual volunteers to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in any of the plurality of clinical trials that are associated with one of the one or more selected clinical trial researchers and have been identified to the recruitment service provider as currently recruiting candidates is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A)(see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97). Furthermore, Michelson et al. teaches in area 650, the user is asked to agree to terms and conditions governing the system and upon completion of the required information and accepting the terms and conditions, the user become a registered users (see: paragraph 97). Moreover,

Michelson et al. teaches at area 607, a registered user may select up to three therapeutic area (clinical research areas) in which the user is interested (see: paragraph 95);

--the claimed comparing the at least one of personal and medical information to selection criteria of any of the plurality of clinical trials that are associated with one or more of the selected clinical trial researchers and have been identified to the recruitment service provider as currently recruiting candidates is met by the system evaluating information with respect to the person's possible selection for a clinical study such as querying the database based on a disease condition of interest indicated by the subject; other information from the registration of the subject or prior questionnaire completed by the subject and the geographic location of the investigator that has been selected to perform the clinical study (see: paragraph 166);

--the claimed selecting the individual as a potential candidate for participating as a research subject in at least one of the identified clinical trials for which the comparison indicates a match is met at step 2050, where after a match, the system provides the person or caregiver with notification of the clinical study (see: paragraph 167); and

--the claimed providing the individual's contact information to a representative of the at least one matching clinical trial, whereby the representative may contact the individual directly to further evaluate the individual as a candidate for participating as a research subject in the matching clinical trial is met after the pre-screening process, a list of pre-screened subjects who may be eligible to participate in a clinical study is given to the investigator and at step 826, the investigator schedule an appointment with each of the subjects on his or her pre-screened list (see: paragraph 114).

As per claim 227, it is rejected for the same reason set forth in claim 205.

As per claim 228, Michelson et al. teaches the steps of:

--the claimed server transmitting a participation agreement for display on one of the plurality of end-user terminals accessible to an individual, the participation agreement soliciting consent from the individual to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in at least one of the plurality of clinical trials that are identified by the recruitment service provider as currently recruiting candidates is met by clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches at step 2040, that after a user has register by completing the registration form, the system asks the person or caregiver to provide simple consent to add the person's information to the database and to give permission to receive notices about clinical studies (see: paragraph 165); and

--the claimed server receiving a signal transmitted by the one of the plurality of end-user terminals indicating the individual's consent to the participation agreement is met when in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97). Furthermore, Michelson et al. teaches in area 650, the user is asked to agree to terms and conditions governing the system and upon completion of the required information and accepting the terms and conditions, the user become a registered users (see: paragraph 97).

As per claim 229, Michelson et al. teaches the claimed step of the server transmitting the health survey form occurs after the server receives the transmitted signal. This feature is met in area 650, the user is asked to agree to terms and conditions governing the system and upon completion of the required information and accepting the terms and conditions, the user become a registered users and at this point the user may choose to answer additional questions such as health survey questions (see: paragraph 97).

As per claims 231, it is rejected for the same reasons set forth in claim 208.

As per claim 232, Michelson et al. teaches the step of:

--the claimed receiving a match query from the representative of the at least one clinical trial, wherein the match query identifies the selection criteria for determining the match is met at step 2146, where the inventive system identifies an investigator based upon the query results and the investigator's practice setting such as the disease condition associated with the specific clinical study used (see: paragraph 147).

As per claim 233, Michelson et al. teaches the claimed information transmitted by the individual includes personally-identifying information of the individual. This limitation is met when a user want to register as a user with the subject database, he or she will be required to provide information such as first and last name, electronic mail address, zip code, medical conditions experienced by the user and telephone number and additional information such as date of birth (see: paragraph 97).

As per claim 234, Michelson et al. teaches the claimed personally-identifying information includes a name of the individual and a second personal identifier of the individual. This limitation is met when a user want to register as a user with the subject database, he or she will

be required to provide information such as first and last name, electronic mail address, zip code, medical conditions experienced by the user and telephone number and additional information such as date of birth (see: paragraph 97).

As per claim 235, Michelson et al. teaches the claimed second personal identifier is a date of birth of the individual. This limitation is met when a user want to register as a user with the subject database, he or she will be required to provide information such as first and last name, electronic mail address, zip code, medical conditions experienced by the user and telephone number and additional information such as date of birth (see: paragraph 97).

As per claim 236, Michelson et al. teaches the claimed personally-identifying information includes a registration number of the individual. This limitation is met by the registration information including user id and password (see: paragraph 10).

As per claim 239, Michelson et al teaches a method of on-line recruitment of volunteers for ongoing consideration as potential candidates for participating as research subjects in any of a plurality of clinical trials, by means of a server operated by a recruitment service provider, the server being configured to communicate with a plurality of end-user computer terminals via a network, the method comprising the steps of:

--the claimed server transmitting a participation agreement for display on one of the plurality of end-user terminals accessible to an individual, the participation agreement soliciting consent from the individual to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in at least one of the plurality of clinical trials that are identified by the recruitment service provider as currently recruiting candidates is met by clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B)

using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches at step 2040, that after a user has register by completing the registration form, the system asks the person or caregiver to provide simple consent to add the person's information to the database and to give permission to receive notices about clinical studies (see: paragraph 165);

--the claimed server receiving a signal transmitted by the one of the plurality of end-user terminals indicating the individual's consent to the participation agreement is met when in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97). Furthermore, Michelson et al. teaches in area 650, the user is asked to agree to terms and conditions governing the system and upon completion of the required information and accepting the terms and conditions, the user become a registered users (see: paragraph 97);

--the claimed server transmitting a health survey form for display on the one of the plurality of end-user terminals, the health survey form soliciting contact information for the individual, and at least one of personal and medical information for the individual, whereby the at least one of the individual's personal and medical information may be used in the selection of candidates to participate as research subjects in one or more of the plurality of clinical trials is met in area 650, the user is asked to agree to terms and conditions governing the system and upon completion of the required information and accepting the terms and conditions, the user become a registered users and at this point the user may choose to answer additional questions

such as health survey questions (see: paragraph 97). In addition, Michelson et al. teaches that the system evaluate information with respect to the person's possible selection for a clinical study such as querying the database based on a disease condition of interest indicated by the subject; other information from the registration of the subject or prior questionnaire completed by the subject and the geographic location of the investigator that has been selected to perform the clinical study (see: paragraph 166);

--the claimed server receiving information transmitted by the individual via the one of the plurality of end-user terminals, the information containing the contact information and at least one of the relevant personal and medical information is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using computer a such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97); and

--the claimed server storing the individual's contact information and the at least one of the individual's personal and medical information in a database, thereby registering the individual for consideration as a candidate for participating as a research subject in any of the plurality of clinical trials that is identified by the recruitment service provider as currently recruiting

candidates, wherein the individual's ongoing consideration comprises consideration for any of the clinical trials registered with the recruitment service provider at or after the time when the individual is first registered by the server is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches that a subject uses the secure web page to answer all questions in the questionnaire and the answers are stored in the subject database with consent from the patient (see: paragraph 113 and Figs. 15A-15F).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 210-214, 223, 238 and 245-253 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0002474 to Michelson et al. and drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patient on the Internet" by PR Newswire (hereafter "Newswire") in view of .

As per claim 210, Michelson et al. teaches a method by which an individual may register as a volunteer to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in any of a plurality of clinical trials, and by which the individual may subsequently opt out of the registration, by means of a server operated by a

recruitment service provider, the server being configured to communicate with a plurality of end-user computer terminals via a network, the method comprising the steps of:

--the claimed server transmitting for display on the one end-user terminal a health survey form soliciting from the individual contact information by which the individual may be contacted, and at least one of the individual's personal and medical information, whereby the individual agrees to volunteer to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in any of the plurality of clinical trials is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97). Furthermore, Michelson et al. teaches in area 650, the user is asked to agree to terms and conditions governing the system and upon completion of the required information and accepting the terms and conditions, the user become a registered users (see: paragraph 97);

--the claimed server receiving first information transmitted by the individual via the one end-user computer terminal, the information containing the individual's contact information, personally-identifying information of the individual and the at least one of the individual's

personal and medical information is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using computer a such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97); and

--the claimed server storing the individual's contact information, the personally-identifying information of the individual and the at least one of the individual's personal and medical information in a database, thereby registering the individual for ongoing consideration as a potential candidate for participating as a research subject in any of the plurality of clinical trials that is identified by the recruitment service provider as currently recruiting candidates, wherein the individual's ongoing consideration comprises consideration for any of the clinical trials registered with the recruitment service provider at or after the time when the individual is first registered by the server is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user

and telephone number (see: paragraph 97). In addition, Michelson et al. teaches that a subject uses the secure web page to answer all questions in the questionnaire and the answers are stored in the subject database with consent from the patient (see: paragraph 113 and Figs. 15A-15F);

--the claimed server receiving second information transmitted by the individual through the one end-user computer terminal or another one of the plurality of end-user computer terminals, the second information including the personally-identifying information of the individual and information indicating the individual's request to withdraw the registration. In addition, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, electronic mail address, zip code, medical conditions experienced by the user and telephone number and additional information such as date of birth (see: paragraph 97); and

--the claimed server comparing the transmitted personally-identifying information with the stored personally-identifying information of the individual is met by the system evaluating information with respect to the person's possible selection for a clinical study such as querying the database based on a disease condition of interest (personally-identifying information) indicated by the subject; other information from the registration of the subject or prior questionnaire (stored personally-identifying information) completed by the subject (see: paragraph 166).

Michelson et al. fails to explicitly teach:

--the claimed personally-identifying information of the individual and information indicating the individual's request to withdraw the registration; and

--the claimed withdrawing the individual's registration when the comparing step indicates a match between the transmitted personally-identifying information and the stored personally-identifying information.

However, Michelson et al. teaches that a user will be required to provide user id and password in order to register with the subject database (see: paragraph 97). This suggests that a password is used to match entered (transmitted) user id/password with stored user id/password information and gain access to perform the functions of the system such as a request to withdrawn registration information. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include using a password to match stored identifying information with entered identifying information within the integrated online interactive form that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subject as taught by Michelson et al. with the motivation of providing security protocols to insure privacy, reliability and accuracy of the information stored and access within the system.

Michelson et al. fails to explicitly teach:

--the claimed personally-identifying information of the individual and information indicating the individual's request to withdraw the registration.

Newswire teaches that individuals may withdraw their consent from participating in the clinical trial and requires that their personal information be removed from the database at any time (see: paragraph 11).

One of ordinary skill in art at the time the invention was made would have found it obvious to include the request to withdraw registration as taught by Newswire within the

integrated online interactive form that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subject as taught by Michelson et al. with the motivation of increasing the efficiency and speed of the clinical trials process (see: paragraph 6).

As per claim 211, Michelson et al. teaches the claimed personally-identifying information includes a name of the individual in combination with a second personal identifier of the individual. This limitation is met when a user want to register as a user with the subject database, he or she will be required to provide information such as first and last name, electronic mail address, zip code, medical conditions experienced by the user and telephone number and additional information such as date of birth (see: paragraph 97).

As per claim 212, Michelson et al. teaches the claimed second personal identifier is a date of birth of the individual. This limitation is met when a user want to register as a user with the subject database, he or she will be required to provide information such as first and last name, electronic mail address, zip code, medical conditions experienced by the user and telephone number and additional information such as date of birth (see: paragraph 97).

As per claim 213, Michelson et al. teaches the claimed personally-identifying information includes a registration number of the individual. This limitation is met by the registration information including user id and password (see: paragraph 10).

As per claim 214, Michelson et al. teaches the claimed first information transmitted by the individual signifies an agreement by the individual to release the contact information to a representative of at least one of one of the registered clinical trials. This limitation is met at step 2040, where after the subject has registered, the inventive system ask the subject for permission

to receive notices about clinical studies (see: paragraph 165). In addition, Michelson et al. teaches that clinical study sponsors, investigators and subjects may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81).

As per claim 223, Michelson et al. teaches that clinical study sponsors, investigators and subjects may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A)(see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97). Furthermore, Michelson teaches that the system evaluate information with respect to the person's possible selection for a clinical study such as querying the database based on a disease condition of interest (personally-identifying information) indicated by the subject; other information from the registration of the subject or prior questionnaire (stored personally-identifying information) completed by the subject (see: paragraph 166).

Michelson et al. fails to teach:

--the claimed second information transmitted by the individual includes information indicating the individual's request to withdraw the registration; and

--the claimed withdrawing the individual's registration when the comparing step indicates a match between the transmitted personally-identifying information and the stored personally-identifying information.

However, Michelson et al. teaches that a user will be required to provide user id and password in order to register with the subject database (see: paragraph 97). This suggests that a password is used to match entered (transmitted) user id/password with stored user id/password information and gain access to perform the functions of the system such as a request to withdrawn registration information. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include using a password to match stored identifying information with entered identifying information within the integrated online interactive form that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subject as taught by Michelson et al. with the motivation of providing security protocols to insure privacy, reliability and accuracy of the information stored and access within the system.

Michelson et al. fails to teach:

--the claimed second information transmitted by the individual includes information indicating the individual's request to withdraw the registration.

Newswire teaches that individuals may withdraw their consent from participating in the clinical trial and requires that their personal information be removed from the database at any time (see: paragraph 11).

The obviousness of combining the teachings of Newswire within the system as taught by Michelson et al. are discussed in the rejection of claim 210, and incorporated herein.

As per claim 238, Michelson et al. teaches that clinical study sponsors, investigators and subjects may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A)(see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97). Furthermore, Michelson teaches that the system evaluate information with respect to the person's possible selection for a clinical study such as querying the database based on a disease condition of interest (personally-identifying information) indicated by the subject; other information from the registration of the subject or prior questionnaire (stored personally-identifying information) completed by the subject (see: paragraph 166).

Michelson et al. fails to teach:

--the claimed second information transmitted by the individual includes information indicating the individual's request to withdraw the registration; and

--the claimed withdrawing the individual's registration when the comparing step indicates a match between the transmitted personally-identifying information and the stored personally-identifying information.

However, Michelson et al. teaches that a user will be required to provide user id and password in order to register with the subject database (see: paragraph 97). This suggests that a

password is used to match entered (transmitted) user id/password with stored user id/password information and gain access to perform the functions of the system such as a request to withdrawn registration information. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include using a password to match stored identifying information with entered identifying information within the integrated online interactive form that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subject as taught by Michelson et al. with the motivation of providing security protocols to insure privacy, reliability and accuracy of the information stored and access within the system.

Michelson et al. fails to teach:

--the claimed second information transmitted by the individual includes information indicating the individual's request to withdraw the registration.

Newswire teaches that individuals may withdraw their consent from participating in the clinical trial and requires that their personal information be removed from the database at any time (see: paragraph 11).

The obviousness of combining the teachings of Newswire within the system as taught by Michelson et al. are discussed in the rejection of claim 210, and incorporated herein.

As per claim 245, Michelson et al. teaches a method by which an individual may register as a volunteer to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in any of a plurality of clinical trials, and by which the individual may subsequently opt out of the registration, by means of a server operated by a

recruitment service provider, the server being configured to communicate with a plurality of end-user computer terminals via a network, the method comprising the steps of:

--the claimed server transmitting a participation agreement for display on one of the plurality of end-user terminals accessible to the individual, the participation agreement soliciting consent from the individual to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in at least one of the plurality of clinical trials that are identified by the recruitment service provider as currently recruiting candidates is met by clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches at step 2040, that after a user has register by completing the registration form, the system asks the person or caregiver to provide simple consent to add the person's information to the database and to give permission to receive notices about clinical studies (see: paragraph 165);

--the claimed server receiving a signal transmitted by the one of the plurality of end-user terminals indicating the individual's consent to the participation agreement is met when in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97). Furthermore, Michelson et al. teaches in area 650, the user is asked to agree to terms and conditions governing the system and upon completion of the required information and accepting the terms and conditions, the user become a registered users (see: paragraph 97);

--the claimed server transmitting for display on the one end-user terminal a health survey form soliciting from the individual contact information by which the individual may be contacted, and at least one of the individual's personal and medical information, whereby the at least one of the individual's personal and medical information may be used in the selection of potential candidates to participate as research subjects in one or more of the plurality of clinical trials is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97). Furthermore, Michelson et al. teaches in area 650, the user is asked to agree to terms and conditions governing the system and upon completion of the required information and accepting the terms and conditions, the user become a registered users (see: paragraph 97);

--the claimed server receiving first information transmitted by the individual via the one end-user computer terminal, the information containing the individual's contact information, personally-identifying information of the individual and the at least one of the individual's personal and medical information is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using computer a such as computers (101, 102, Fig.

1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97); and

--the claimed server storing the individual's contact information, the personally-identifying information of the individual and the at least one of the individual's personal and medical information in a database, thereby registering the individual for ongoing consideration as a potential candidate for participating as a research subject in any of the plurality of clinical trials that is identified by the recruitment service provider as currently recruiting candidates, wherein the individual's ongoing consideration comprises consideration for any of the clinical trials registered with the recruitment service provider at or after the time when the individual is first registered by the server is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97). In addition, Michelson et al. teaches that a subject

uses the secure web page to answer all questions in the questionnaire and the answers are stored in the subject database with consent from the patient (see: paragraph 113 and Figs. 15A-15F);

--the claimed server receiving second information transmitted by the individual through the one end-user computer terminal or another one of the plurality of end-user computer terminals, the second information including the personally-identifying information of the individual and information indicating the individual's request to withdraw the registration. In addition, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, electronic mail address, zip code, medical conditions experienced by the user and telephone number and additional information such as date of birth (see: paragraph 97); and

--the claimed server comparing the transmitted personally-identifying information with the stored personally-identifying information of the individual is met by the system evaluating information with respect to the person's possible selection for a clinical study such as querying the database based on a disease condition of interest (personally-identifying information) indicated by the subject; other information from the registration of the subject or prior questionnaire (stored personally-identifying information) completed by the subject (see: paragraph 166).

Michelson et al. fails to explicitly teach:

--the claimed personally-identifying information of the individual and information indicating the individual's request to withdraw the registration; and

--the claimed withdrawing the individual's registration when the comparing step indicates a match between the transmitted personally-identifying information and the stored personally-identifying information.

However, Michelson et al. teaches that a user will be required to provide user id and password in order to register with the subject database (see: paragraph 97). This suggests that a password is used to match entered (transmitted) user id/password with stored user id/password information and gain access to perform the functions of the system such as a request to withdrawn registration information. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include using a password to match stored identifying information with entered identifying information within the integrated online interactive form that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subject as taught by Michelson et al. with the motivation of providing security protocols to insure privacy, reliability and accuracy of the information stored and access within the system.

Michelson et al. fails to explicitly teach:

--the claimed personally-identifying information of the individual and information indicating the individual's request to withdraw the registration

Newswire teaches that individuals may withdraw their consent from participating in the clinical trial and requires that their personal information be removed from the database at any time (see: paragraph 11).

As per claims 246-248, they are rejected for the same reasons set forth in claims 211-213.

As per claim 249, Michelson et al. teaches that clinical study sponsors, investigators and subjects may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A)(see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97). Furthermore, Michelson teaches that the system evaluate information with respect to the person's possible selection for a clinical study such as querying the database based on a disease condition of interest (personally-identifying information) indicated by the subject; other information from the registration of the subject or prior questionnaire (stored personally-identifying information) completed by the subject (see: paragraph 166).

Michelson et al. fails to teach:

--the claimed information transmitted by the individual includes information indicating the individual's request to withdraw the registration; and

--the claimed withdrawing the individual's registration when the comparing step indicates a match between the transmitted personally-identifying information and the stored personally-identifying information.

However, Michelson et al. teaches that a user will be required to provide user id and password in order to register with the subject database (see: paragraph 97). This suggests that a

password is used to match entered (transmitted) user id/password with stored user id/password information and gain access to perform the functions of the system such as a request to withdrawn registration information. Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include using a password to match stored identifying information with entered identifying information within the integrated online interactive form that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subject as taught by Michelson et al. with the motivation of providing security protocols to insure privacy, reliability and accuracy of the information stored and access within the system.

Michelson et al. fails to teach:

--the claimed information transmitted by the individual includes information indicating the individual's request to withdraw the registration.

Newswire teaches that individuals may withdraw their consent from participating in the clinical trial and requires that their personal information be removed from the database at any time (see: paragraph 11).

The obviousness of combining the teachings of Newswire within the system as taught by Michelson et al. are discussed in the rejection of claim 210, and incorporated herein.

As per claims 250-252, they are rejected for the same reasons set forth in claim 211-212.

As per claim 253, Michelson et al. teaches the claimed personally-identifying information includes a unique registration number of the individual. This limitation is met when a user want to register as a user with the subject database, he or she will be required to provide information such as first and last name, electronic mail address, zip code, medical conditions experienced by

the user and telephone number and additional information such as date of birth (see: paragraph 97).

9. Claim 222 and 237 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0002474 to Michelson et al. in view of drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patient on the Internet" by PR Newswire (hereafter "Newswire").

As per claim 222, Michelson et al. teaches that clinical study sponsors, investigators and subjects may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A)(see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97).

Michelson et al. fails to explicitly teach the claimed opt-out form including indication that the individual wishes to withdraw from being considered as a potential candidate for participating in any of the plurality of clinical trials.

Newswire teaches that individuals may withdraw their consent from participating in the clinical trial and requires that their personal information be removed from the database at any time (see: paragraph 11).

One of ordinary skill in art at the time the invention was made would have found it obvious to include the request to withdraw registration as taught by Newswire within the integrated online interactive form that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subject as taught by Michelson et al. with the motivation of increasing the efficiency and speed of the clinical trials process (see: paragraph 6).

As per claim 237, Michelson et al. teaches that clinical study sponsors, investigators and subjects may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A)(see: paragraphs 80-81). In addition, Michelson et al. teaches a registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97).

Michelson et al. fails to explicitly teach the claimed opt-out form including indication that the individual wishes to withdraw from being considered as a potential candidate for participating in any of the plurality of clinical trials.

Newswire teaches that individuals may withdraw their consent from participating in the clinical trial and requires that their personal information be removed from the database at any time (see: paragraph 11).

One of ordinary skill in art at the time the invention was made would have found it obvious to include the request to withdraw registration as taught by Newswire within the integrated online interactive form that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subject as taught by Michelson et al. with the motivation of increasing the efficiency and speed of the clinical trials process (see: paragraph 6).

10. Claims 230, 240 and 241-244 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0002474 to Michelson et al. in view of U.S. Patent No. 6,171,112 to Clark.

As per claim 230, Michelson et al. teaches at step 2040, that after a user has register by completing the registration form, the system asks the person or caregiver to provide simple consent to add the person's information to the database and to give permission to receive notices about clinical studies (see: paragraph 165).

Michelson fails to explicitly teach the claimed participation agreement is a click-wrap agreement.

Clark et al. teaches a method and apparatus for authenticating informed consent for patient that includes providing a means for the patient to input data in the form of answers to questions as well as prompting the patient for electronic signature (see: column 11, lines 66 to column 12, lines 50 and Fig. 17).

One of ordinary skill in the art at the time the invention was made would have found it obvious to include authenticating informed consent for patient as taught by Clark et al. within the integrated online interactive form that promotes exchange of information among clinical study

sponsors, clinical study investigators, and potential clinical study subject as taught by Michelson et al. with the motivation of positively affecting the patient-physician relationship by allowing the physician to accomplish more with each patient in less time (see: Clark et al.: column 3, lines 37-40).

As per claim 240, Michelson et al. teaches at step 2040, that after a user has register by completing the registration form, the system asks the person or caregiver to provide simple consent to add the person's information to the database and to give permission to receive notices about clinical studies (see: paragraph 165).

Michelson fails to explicitly teach the claimed participation agreement is a click-wrap agreement.

Clark et al. teaches a method and apparatus for authenticating informed consent for patient that includes providing a means for the patient to input data in the form of answers to questions as well as prompting the patient for electronic signature (see: column 11, lines 66 to column 12, lines 50 and Fig. 17).

One of ordinary skill in the art at the time the invention was made would have found it obvious to include authenticating informed consent for patient as taught by Clark et al. within the integrated online interactive form that promotes exchange of information among clinical study sponsors, clinical study investigators, and potential clinical study subject as taught by Michelson et al. with the motivation of positively affecting the patient-physician relationship by allowing the physician to accomplish more with each patient in less time (see: Clark et al.: column 3, lines 37-40).

As per claim 241, Michelson et al. teaches the claimed health survey form solicits the identification of one or more medical conditions of the individual for which the individual wishes to be considered as a potential candidate for participating as a research subject in one or more of the plurality of clinical trials. This limitation is met by the registration questionnaire used by subjects to enter information about themselves into system (100, Fig. 1) and designed to access eligibility for a given clinical study (see: paragraph 82). Additionally, Michelson et al. teaches that in order to become a user registered with the subject database, the user will be required to provide information such as an indication of one or more medical conditions in which the user is interested (see: paragraph 97).

As per claim 242, Michelson et al. teaches the claimed health survey form solicits the identification of one or more clinical researchers for whom the individual wishes to be considered as a potential candidate for participating as a research subject in any of the plurality of clinical trials that are associated with the one or more clinical researchers. This feature is met at area 607, where a registered user may select up to three therapeutic area (clinical research areas) in which the user is interested (see: paragraph 95).

As per claim 243, Michelson et al. teaches the claimed network comprises one or more of the Internet, the World Wide Web, an intranet, a local area network, a wide area network and a wireless communications network. The limitation is met by the network (103, Fig. 1A) being the Internet (see: paragraph 80).

As per claim 244, Michelson et al. teaches the claimed step of:

--the claimed server transmitting registration information for display on a second end-user computer terminal, said registration information soliciting information for registering a clinical

researcher administering one or more of the plurality of clinical trials. This feature is met by the clinical study sponsors, investigators and subjects that may access the system (100, Fig. 1B) using a computer such as computers (101, 102, Fig. 1A) including workstations or servers capable of communicating via a network (103, Fig. 1A) (see: paragraphs 80-81). In addition, Michelson et al. teaches that an investigator who is interesting in conducting a clinical study may register on the professional site (see: paragraph 99 and Figs. 1B, 7A-7C).

***Response to Amendment***

11. Applicant's arguments filed 11/10/06 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 11/10/06.

(A) In the remarks, Applicants argues in substance that, the Provisional 60/178634 (hereinafter '634) fails to provide a sufficient basis for finding that the inventors of the subject matter disclosed by Michelson US Patent Pub. Application 2002/0002474 (hereinafter '474) were in possession of the subject matter presently relied upon by the Examiner at the time Michelson's filing of the Provisional '634, in particular paragraphs 10, 95, 97, 99, 113, 114, 165 and 167 of Michelson's. The Examiner respectfully submit that paragraph 10 of Michelson recites "...registration information including user id and password (see: paragraph 10)" to read on a claim 236 limitation and page 7, lines 12-14 of the Provisional recites "a patient database is constructed as to protect the patient's privacy, and includes information about individual patient's such as relevant clinical data, zip code of residence, and e-mail address". In addition, page 9, lines 4-6 of the Provisional also reads "communication between users of the web site through e-mail are secure through authentication...account sign up...core personalization and

registration infrastructure supports ad-hoc user properties, profile". This clearly indicates that the account sign up using authentication with a user profile are stored in a patient database reading on "personally-identifying information including a registration number of the individual" as recited claim 236.

Paragraph 95 of Michelson recites "...at area 607, where a registered user may select up to three therapeutic area (clinical research areas) in which the user is interested (see: paragraph 95)" to read on a claim 242 limitation and page 10, lines 4-5 of the Provisional recites "the inventive system software enables patient to identify clinical trials for which they may enroll". This clearly indicates that the patient may select or "identify one or more clinical researchers for whom the individual wishes to be considered as a potential candidate for participating as a research subject" as recited in claim 242.

Paragraph 97 of Michelson recites "...in order to become a user registered with the subject database, the user will be required to provide information such as first name, date of birth, electronic mail address, zip code, medical conditions experienced by the user and telephone number (see: paragraph 97)" to read on a claim 204 limitation and page 7, lines 12-14 of the Provisional recite "a patient database is constructed as to protect the patient's privacy, and includes information about individual patient's such as relevant clinical data, zip code of residence, and e-mail address". This describes that a user may register using a secure web site to enter information into the patient database including contact information such as zip code of residence, and e-mail address by which the individual may be contacted as recited in claim 204.

Paragraph 99 of Michelson recites "...that an investigator who is interesting in conducting a clinical study may register on the professional site (see: paragraph 99 and Figs. 1B,

7A-7C)" to read on a claim 209 limitation and page 6 line 21 to page 7, line 2 of the Provisional recites "investor database includes information about the doctor who perform clinical trials, such as name, address, DEA#, trial study experiences, number of studies conducted, when studies were conducted, medical school history, etc...". This clearly indicates that the investigator registers using a secure web site to enter information such doctors who perform clinical trials into the investor database.

Paragraph 113 of Michelson recites "...a subject uses the secure web page to answer all questions in the questionnaire and the answers are stored in the subject database (see: paragraph 113 and Figs. 15A-15F)" to read on a claim 210 limitation and page 7, lines 12-14 of the Provisional recite "a patient database is constructed as to protect the patient's privacy, and includes information about individual patient's such as relevant clinical data, zip code of residence, and e-mail address". This suggests that using a web page the user answers question such zip code and relevant clinical data, which is stored in the patient database.

Paragraph 114 of Michelson recites "...pre-screening process, a list of pre-screened subjects who may be eligible to participate in a clinical study is given to the investigator and at step 826, the investigator schedule an appointment with each of the subjects on his or her pre-screened list (see: paragraph 114)" to read on a claim 215 limitation and page 9, lines 14-17 of the Provisional recites "software includes proprietary database matching that enables a comparison of the participant profile to the trials protocol criteria. For example, templates are established for certain protocols and performing database matching to compare this information against the participant entered data". In addition, on page 7, lines 12-14 of the Provisional recites "a patient database is constructed as to protect the patient's privacy, and includes information

about individual patient's such as relevant clinical data, zip code of residence, and e-mail address". This clearly shows that a match step is performed and the patient database including an e-mail address can be used to contact an eligible participant as recited in claim 215.

Paragraph 165 of Michelson recites "...at step 2040, where after the subject has registered, the inventive system ask the subject for permission to receive notices about clinical studies (see: paragraph 165)" to read on a claim 216 limitation and page 9, lines 14-17 of the Provisional recites "software includes proprietary database matching that enables a comparison of the participant profile to the trials protocol criteria. For example, templates are established for certain protocols and performing database matching to compare this information against the participant entered data". In addition, on page 10, lines 4-5 of the Provisional recites "Finally, the inventive system software enables patient to identify clinical trials for which they may enroll". This suggests an agreement by the individual to release the contact information to the representative of the at least one matching clinical trial by enrolling after a match as recited in claim 216.

Paragraph 167 of Michelson recites "...at step 2050, where after a match, the system provides the person or caregiver with notification of the clinical study (see: paragraph 167)" to read on a claim 226 limitation and page 9, lines 14-17 of the Provisional recites "software includes proprietary database matching that enables a comparison of the participant profile to the trials protocol criteria. For example, templates are established for certain protocols and performing database matching to compare this information against the participant entered data". In addition, on page 10, lines 4-5 of the Provisional recites "Finally, the inventive system software enables patient to identify clinical trials for which they may enroll". This suggests

selecting an individual as a potential candidate for participating as a research subject in at least one of the identified clinical trials for which the comparison indicates a match as recited in claim 226.

With regard to Board of Patent Appeals and Interferences (BPAI) response to Application 09/923385, the Examiner respectfully that passage relied on in that case are different from the passage relied on for the instant application (09/556945) and therefore, the BPAI response does not apply here.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Morgan whose telephone number is (571) 272-6773. The examiner can normally be reached on 8:30 a.m. - 5:00 p.m. Mon - Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 3626